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510(k) SUMMARY

Premarket Notification: K113405

January 9, 2011

DEVICE: Suspension™ Clavicle Fracture Fixation System

SPONSOR/MANUFACTURER:

Suspension Orthopaedic Solutions, LLC
1507 Ritchie Highway – Suite 101
Arnold, MD 21012

SUMBITTER/REGULATORY CONTACT:

Curtis Raymond
Orchid Design
80 Shelton Technology Center
Shelton, CT 06484
Tel: 203-922-0105

FDA ESTABLISHMENT REGISTRATION NUMBER: 3008770958

TRADE NAME, COMMON NAME, CLASSIFICATION:

TRADE NAME:	Suspension™ Clavicle Fracture Fixation System
COMMON NAME:	Clavicle Plate
PRODUCT CODE:	HRS
	HWC
CLASSIFICATION:	Class II - ref.: 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories

PREDICATE DEVICE(S):

Suspension™ Clavicle Fracture Fixation System (K102095)

DESCRIPTION OF SUBJECT DEVICE:

The current Clavicle Fracture Fixation System accommodates fractures covering the mid-section and distal portions of the clavicle. As proposed in this 510(k) notification, the sponsor wishes to extend the product line by including a plate specifically designed for mid-shaft (i.e., non-distal) clavicle fractures. Because the proposed mid-shaft plate would not cover the distal aspect of the clavicle, its design will be slightly different. The proposed mid-shaft plate will be approximately 2/3 of the length of the current large size clavicle plate. Because the proposed mid-shaft plate will

not engage the articular capsule of the clavicle, the distal screw holes of the current plate are eliminated.

The proposed mid-shaft plate will be available in one size only with an overall length of approximately 100mm. The thickness of the plate will be the same as the Suspension™ clavicle plates now on the market. Likewise, the width of the mid-shaft plate will be the same as the mid-shaft portion of the current plates. The screws used to secure the proposed mid-shaft plate to the clavicle are the same as those used for the current Suspension™ clavicle plates.

As with the current Suspension™ Clavicle Fracture Fixation plates, the proposed mid-shaft plate will be composed exclusively of 316L stainless steel. Implantable components are intended for re-sterilization, but are for single-use only.

A hex driver with a handle and a hex driver shaft for hand-tightening bone screws is supplied with the device. These accessories are intended for re-use and re-sterilization. Drill bits are required for creating pilot holes for bone screws. These drill bits are included supplied with the clavicle plates and are steam sterilized by the hospital or surgical center.

INTENDED USE:

The Suspension™ Clavicle Fracture Fixation System can be used for adult patients. The Suspension™ Clavicle Fracture Fixation plates and screws are indicated for fixation of clavicle fractures.

PERFORMANCE CHARACTERISTICS:

Performance characteristics of the proposed mid-shaft plate have not changed from those described in K102095. Functional test conducted in accordance with ASTM F382-99 shows the device to have equivalent performance characteristics as the predicate Suspension™ Clavicle Fracture Fixation System plate.

SAFETY CHARACTERISTICS:

Implantable components of the Suspension™ Clavicle Fracture Fixation System as well as the accessory surgical instruments are supplied non-sterile and are to be steam sterilized by hospital personnel. There have been no changes to the cleaning or sterilization methods from those described in K102095.

The subject device is a permanent implant. All metal parts are composed of 316L stainless steel. Keeping in mind the nature of these materials, new biosafety testing was not conducted by the sponsor. None of these materials has changed from those described in K102095.

CONCLUSION(S):

The proposed modification consists solely of a line extension of the existing Suspension™ Clavicle Fracture Fixation System to address clavicle fractures not involving distal fractures. The subject device has the same design considerations, assembly configurations, materials, performance characteristics and indications for use as the predicate device. The subject has the same safety and efficacy profile as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Suspension Orthopaedic Solutions, LLC
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Shelton, Connecticut 06484

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Re: K113405
Trade/Device Name: Suspension™ Clavicle Fracture Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: December 14, 2011
Received: December 16, 2011

Dear Mr. Raymond

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113405

Indications for Use

510(k) Number (if known): K113405

Device Name: Suspension™ Clavicle Fracture Fixation System

The Suspension™ Clavicle Fracture Fixation System can be used for adult patients. The Suspension™ Clavicle Fracture Fixation plates and screws are indicated for fixation of clavicle fractures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Elizabeth Francis

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113405